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INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

| Applicant's or agent's file reference NO 7264MO | | | nt's file reference | FOR FURTHER AC | ACTION See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416) | | | |
|---|--|-----------|---|---|--|--------------------------|--|--|
| 1 | International application No. PCT/EP 03/07269 | | | International filing date (day/month/year) 07.07.2003 | | h/year) | Priority date (day/month/year) 15.07.2002 | |
| | nationa G3/30 | | nt Classification (IPC) or be | nth national classification an | nd IPC | | · | |
| Appli SOC | | DES | S PRODUITS NESTL | E S.A. et al. | | | | |
| 1. | This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36. | | | | | | | |
| 2. | 2. This REPORT consists of a total of 5 sheets, including this cover sheet. | | | | | | | |
| | This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT). | | | | | | | |
| | These annexes consist of a total of sheets. | | | | | | | |
| 3. | This | repoi | t contains indications re | elating to the following ite | ems: | | | |
| | 1 | × | Basis of the opinion | | , | | | |
| | II | | Priority | | | | | |
| | 111 | | Non-establishment of | opinion with regard to no | ovelty, i | nventive step a | and industrial applicability | |
| | IV | | Lack of unity of invent | ion | | | | |
| | V Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability citations and explanations supporting such statement | | | | | | nventive step or industrial applicability; | |
| ł | VI | | Certain documents cit | | | | | |
| | VII Certain defects in the international application | | | | | | | |
| | VIII | | Certain observations | on the international appli | ication | | • | |
| Date of submission of the demand Date of completion of this report | | | | | | his report | | |
| 03. | 03.12.2003 | | | 20.10.2004 | | | | |
| Nam preli | preliminary examining authority: | | | | Author | ized Officer | Junior Petragan | |
| _ | 9) | D-≀ Te | ropean Patent Office 80298 Munich I. +49 89 2399 - 0 Tx: 523 x: +49 89 2399 - 4465 | 656 epmu d | Gaise Teleph | er, M none No. +49 89 | 2399-2383 | |

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.

PCT/EP 03/07269

| I. | Basi | s of | the | re | por | 1 |
|----|------|------|-----|----|-----|---|
|----|------|------|-----|----|-----|---|

 With regard to the elements of the international application (Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17)):

| | Des | cription, Pages | | | | |
|---|---|--|---|--|--|--|
| | 1-9 | | as originally filed | | | |
| | | | | | | |
| | Clair | ms, Numbers | | | | |
| | 1-24 | | as originally filed | | | |
| With regard to the language, all the elements marked above were available or furnished to this Authority language in which the international application was filed, unless otherwise indicated under this item. | | | | | | |
| These elements were available or furnished to this Authority in the following language: , which is: | | | | | | |
| | | the language of a trai | nslation furnished for the purposes of the international search (under Rule 23.1(b)). | | | |
| | | the language of public | cation of the international application (under Rule 48.3(b)). | | | |
| | | the language of a train Rule 55.2 and/or 55.3 | nslation furnished for the purposes of international preliminary examination (under 8). | | | |
| 3. | 3. With regard to any nucleotide and/or amino acid sequence disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing: | | | | | |
| | | contained in the inter | national application in written form. | | | |
| | | filed together with the | e international application in computer readable form. | | | |
| | | furnished subsequen | tly to this Authority in written form. | | | |
| | | furnished subsequen | tly to this Authority in computer readable form. | | | |
| | | The statement that the in the international ap | ne subsequently furnished written sequence listing does not go beyond the disclosure oplication as filed has been furnished. | | | |
| | | The statement that the listing has been furni | ne information recorded in computer readable form is identical to the written sequence shed. | | | |
| 4. | The | amendments have re | esulted in the cancellation of: | | | |
| | | the description, | pages: | | | |
| | | the claims, | Nos.: | | | |
| | | the drawings, | sheets: | | | |
| 5. | | This report has been been considered to g | established as if (some of) the amendments had not been made, since they have go beyond the disclosure as filed (Rule 70.2(c)). | | | |
| | | (Any replacement sh | neet containing such amendments must be referred to under item 1 and annexed to this | | | |
| 6. | Add | litional observations, i | if necessary: | | | |

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.

PCT/EP 03/07269

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)

Yes: Claims No: Claims 1-24

Inventive step (IS)

Yes: Claims

20-22

No: Claims

1-19,23,24

Industrial applicability (IA)

Yes: Claims

1-24

No: Claims

2. Citations and explanations

see separate sheet

Re Item V

Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Reference is made to the following documents:

D1: WO 01 93694 A (CAPRICORN PHARMA INC) 13 December 2001 (2001-12-13)

D2: US-A-4 370 350 (FISHER E EUGENE ET AL) 25 January 1983 (1983-01-25)

2. Document D1, which is considered to represent the most relevant state of the art, discloses (cf. page 24, line 21 - p. 26, l. 17) a chewing gum (see in particular p. 26, l. 4-17) incorporating at least one tablet (in part. p. 24, l. 21-27, and examples 1-20), thus forming at least two integral parts. From this composite product the subject-matter of claim 1 differs in that the chewing gum known from D1 is not disclosed to be tablet pressed itself.

From e.g. D2 it is however known to use methods of tablet pressing for manufacturing chewing gum because this allows taking advantage of conventional tablet pressing equipment and working at high speed (see column 1, I. 59-68). It is further known that the chewing gums to be compressed should comprise a bulking agent (col. 2, I. 23-62).

The man skilled in the art of producing chewing gum comprising active ingredients would thus consider, starting from D1, to use the tablet pressing equipment already present, as suggested by D2, and would thus arrive at the product defined in claim 1 without employing an inventive step (Article 33(3) PCT).

- The obvious combination of D1 and D2 (see above) would inevitably lead to a process as defined in claim 23, which process is thus not inventive, either (Article 33(3) PCT).
- Dependent claims 2-19 and 24 are only allowable when related to an allowable independent claim.
- 5. The method of claim 20 differs from the one known from D1, which is considered as representing the closest available prior art, in that it prescribes a layered

INTERNATIONAL PRELIMINARY International application No. PCT/EP 03/07269 EXAMINATION REPORT - SEPARATE SHEET

configuration of both the chewing gum part and the tablet base part in a composite product, in which both integral parts are tablet pressed. D1 discloses the incorporation of tablet shaped integral parts into a chewing gum, without hinting at forming a layered product.

None of the available prior art documents would give the man skilled in the art the incentive to include layered tablet pressed parts into layers of chewing gum. The subject-matter of claim 20, and its dependent claims 21 and 22, is thus considered being new (Article 33(2) PCT) and including an inventive step (Article 33(3) PCT).